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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,126

03/17/2004

James Robert Schwartz

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27752 7590 03/04/2009
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EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

03/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,126	Applicant(s) SCHWARTZ ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/17/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8,11,12,14,15 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,11,12,14,15 and 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/13/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 4-7, 9, 10, 13 and 16 have been cancelled. Claim 28 is new. Claims 1-3, 8, 11, 12, 14, 15 and 17-28 are pending. Applicant's amendment and newly filed IDS have necessitated a new ground of rejection.

Accordingly, this action is FINAL.

Terminal Disclaimer

The terminal disclaimer filed on 11/17/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending application 10/802166 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Withdrawn rejections:

Applicant's amendments and arguments filed 10/23/07 and 2/14/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Applicant's amendments and arguments have overcome the rejections of record and those rejections are withdrawn by the Examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 8, 11, 12, 14, 15 and 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 2003/0215522 filed on 3/18/03 with the provisional application filed on 4/22/02 (Applicant supplied on IDS filed 2/13/08)).

Applicant claims a composition comprising a pyrithione and hydroxyl-containing basic zinc carbonate and methods of treating microbial infections and dandruff.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Johnson et al. teach compositions and methods of treating microbial infections, fungal infections and dandruff (claims 1-46 and see examples 1-54 and [0211-0215]).

Art Unit: 1616

Johnson et al. teach in the abstract compositions comprising an effective amount of a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25 degree C.; from about 5% to about 50% of a surfactant; and from about 40% to about 95% water; wherein the pH of the composition is greater than about 7. Further disclosed are compositions comprising an effective amount of a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25 degree C.; from about 5% to about 50% of a surfactant; and from about 0.1% to about 5% of a zinc ionophoric material; from about 40% to about 95% water; and wherein the pH of the composition is greater than about 7. Johnson et al. teach claim 20 a composition comprising: a. an effective amount of a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25.degree. C.; b. from about 5% to about 50% of a surfactant; and c. from about 0.1% to about 5% of a zinc ionophoric material; d. from about 40% to about 95% water; and wherein the pH of the composition is greater than about 7. Johnson et al. teach in claims 23 and 24: A composition according to claim 20 wherein the zinc ionophoric material is pyrrhione or a **zinc salt of pyrrhione**; and in claim 24 a composition according to claim 23 wherein the zinc ionophoric material is zinc pyrrhione. Johnson et al. teach in claims 33-35: The composition according to claim 27 wherein the zinc-containing layered material is selected from the group consisting of **basic zinc carbonate hydroxide**, zinc copper carbonate, copper zinc carbonate hydroxide, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double

Art Unit: 1616

salts and mixtures thereof. The composition according to claim 27 wherein the zinc-containing layered material is selected from the group consisting of zinc hydroxycarbonate, hydrozincite, basic zinc carbonate and mixtures thereof.

The composition according to claim 34 wherein the zinc-containing layered material is hydrozincite or **basic zinc carbonate**. Zinc compounds are listed in [0038-0057].

Methods of manufacture are disclosed and can be prepared by any known or otherwise effective technique [0209] and [0221]. Materials can be made in situ or during a production process [0037].

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Johnson et al. do not expressly teach a composition wherein the ratio of zinc-containing layered material to pyrithione is from about 1:2 to about 3:1 or from about 5:100 to about 10:1 or an augmentation factor of greater than 1.3 or 1.5.

2. Johnson et al. do not expressly teach a method of preparing a personal care composition comprising in situ reaction of carbonate salt with a zinc salt wherein the ratio of zinc hydroxide to sodium carbonate is between about 1:10 and about 10:1.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Johnson et al. wherein the ratio of zinc-containing layered material to pyrithione is from about 1:2 to about 3:1 or from about 5:100 to about 10:1 or an augmentation factor of greater than 1.3 or 1.5. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Johnson et al. suggest the weight ratios to use which embrace the instantly claimed amounts, which intrinsically has the instantly claimed augmentation factors, and then it is merely optimization of those amounts to arrive at the instantly claimed limitations. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of preparing a personal care composition of Johnson et al. comprising in situ reaction of carbonate salt with a zinc salt wherein the ratio of zinc hydroxide to sodium carbonate is between about 1:10 and about 10:1, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Johnson et al. teach forming the compounds in situ and name the instantly claimed zinc containing layered material: basic zinc carbonate. It is then merely optimization of starting materials, a zinc source such as zinc oxide and a carbonate source such as sodium bicarbonate to make the end product (See [0207]). The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

Art Unit: 1616

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 8, 11, 12, 14, 15 and 17-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 17, 27-31 and 40 of copending Application No. 11/602,770 (PGPUB 2007/0128147 on the IDS filed on 2/13/08). The copending application teaches compositions and methods of preparing the compositions comprising a particulate zinc material such as basic zinc carbonate and zinc pyrithione (claims 1, 2, 17, 27-31 and 40).

The copending application does not expressly teach how much basic zinc carbonate to add to arrive at the instantly claimed ratio or augmentation factors.

However, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize and would intrinsically have the same augmentation factor. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Therefore, one of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2/13/08 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**

FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616